

Supplementary materials 1: Summary of ethical approval submissions

STAGE 1			DMU ethics	IRAS	R&D
Description	Précis of amendment	Paperwork submitted	Date approved	Date approved	Date of approval
Original ethics application	Original submission requesting approval for stage 1 and stage 2 of the project, including recruitment of Health Visitors and parents.	Protocol version 3 Appendix 1: Flowchart Participant Invitation Letter Interview Participant Invitation Letter Focus Group PIS for Focus group participation PIS for Stage 2 interviews PIS for Parents in the longitudinal group in year 2 of the study Participant Consent Form Focus Group Participant Consent Form Interview Participant Assent form Information sheet and letter HV HV Provisional Consent form HV Full Consent Form HV log (SystemOne) Parental Provisional Consent GP letter Demographic and feeding questions Form for interview about materials developed in study Focus group rating scale Evidence of sponsor insurance Letter from NIHR Letter from sponsor CTU letter/proposal CV for ISJR Questionnaires: EQ5D, dep/anx scale, PSI, MMQ	27/8/14	17/11/14	20/1/15

STAGE 1			DMU ethics	IRAS	R&D
	Précis of amendment	Paperwork submitted	Date of approval	Date of approval	Date of approval
Amendment 1: Widening recruitment (Non-substantial amendment)	Including additional health centres; fliers for mother & baby groups at LPT centres; recruiting at non-NHS sites by fliers & researcher attendance	Protocol version 4 (dated 19/3/15) NHS flier Non-NHS flier	30/3/15	22/4/15	6/5/15
Amendment 2: Package development (SA1)	Requesting permission from parents already recruited into the study to use quotes and/or experiences to be used in the package, either in written or video form.	Protocol version 4 (dated 17/8/15) Information sheet Consent form	11/9/15	25/9/15	7/10/15
Amendment 3: SystmOne (SA2)	Permission to collect, record and review routine data on SystmOne regarding crying from parents visited by Health Visitors.	Protocol version 5 (dated 10/9/15) including appendix 2 Protocol version 6 (dated 20/10/15)	6/11/15	21/10/15	Confirm approval not needed 21/11/15

STAGE 2			DMU ethics	IRAS	R&D
	Précis of amendment	Paperwork submitted	Date of approval	Date of approval	Date approval
Amendment 4: Stage 2 paperwork (SA3)	Approval for revised recruitment paperwork and strategy, elements of package, outcome measures	Protocol version 7 Recruitment & assessment flowchart Safeguarding info and flowchart Website printed version CBT practitioners manual List of baseline and outcome measures Demographic information Wellness questionnaires Baby's crying, feeding and health questionnaires Evaluation of SC materials Crying knowledge scale RCT compliance and CBT costs HV questionnaire re Stage 2 Information booklet Summary of website video content	26/1/16	12/2/16	2/3/16
Amendment 5: Widening recruitment for stage 2 (SA4)	Including additional health and children's centres and HV teams; recruiting at NHS and non-NHS sites via fliers, and at non-NHS sites via researcher attendance	Protocol version 8 Recruitment flier (same for NHS and non-NHS)	25/4/16	13/6/16	